I

108TH CONGRESS
2D SESSION

H. R. 4790

To amend the Federal Food, Drug, and Cosmetic Act to authorize the importation of prescription drugs from Canada and certain other countries, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

JULY 9, 2004

Mr. JOHN introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To amend the Federal Food, Drug, and Cosmetic Act to authorize the importation of prescription drugs from Canada and certain other countries, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Drug Importation Promotion and Safety Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

SEC. 2. IMPORTATION OF PRESCRIPTION DRUGS; OFFICE OF DRUG IMPORTATION PROMOTION AND SAFETY; OTHER GENERAL PROVISIONS.

Chapter VIII of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended—

(1) by inserting after the chapter heading the following:

"Subchapter A—General Provisions"; and

(2) by adding at the end the following:

"Subchapter B—Importation of Prescription Drugs

"SEC. 811. GENERAL PROVISIONS.

"(a) OFFICE OF DRUG IMPORTATION PROMOTION AND SAFETY.—There is established within the Office of the Commissioner of Food and Drugs an office to be known as the Office of Drug Importation Promotion and Safety, which shall be headed by an Associate Commissioner appointed by the Commissioner. The Commissioner of Food and Drugs shall carry out this subchapter acting through such Associate Commissioner.

''(b) ANNUAL REPORT.—The Secretary shall annually submit to the Congress a report on activities carried out under this subchapter, including a determination by the Secretary of whether prescription drugs imported under this subchapter are safe and effective.

''(c) DEFINITIONS.—For purposes of this subchapter:

''(1) DRUG IMPORTATION FACILITY.—The term 'drug importation facility' means a person, other than an individual importing a prescription drug under section 814, located outside the United States (other than a transporter) that engages in the distribution or dispensing of a prescription drug that is imported or offered for importation into the United States.

''(2) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person, other than an individual importing a prescription drug under section 814, that offers to dispense in the United States a prescription drug through an Internet website in interstate commerce, regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(3) PHARMACY.—The term 'pharmacy' means a person, other than an individual importing a pre-

scription drug under section 814, licensed by a State to dispense prescription drugs or to provide pharmaceutical care.

''(4) PERMITTED COUNTRY.—The term 'permitted country' means—

''(A) Australia;

''(B) a member country of the European Union as of January 1, 2003;

''(C) Japan;

''(D) New Zealand;

''(E) Switzerland; and

''(F) such additional countries as the Secretary may specify.

''(5) PRESCRIPTION DRUG.—

''(A) IN GENERAL.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(B) EXCLUSIONS.—The term 'prescription drug' does not include—

''(i) a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802));

"(ii) a biological product (as defined in section 351 of the Public Health Service Act (42 U.S.C. 262));

"(iii) an infused drug (including a peritoneal dialysis solution);

"(iv) an intravenously injected drug;

"(v) a drug that is inhaled during surgery;

"(vi) a parenteral drug;

"(vii) a drug manufactured through 1 or more biotechnology processes, including—

"(I) a therapeutic DNA plasmid product;

"(II) a therapeutic synthetic peptide product of not more than 40 amino acids;

"(III) a monoclonal antibody product for in vivo use; and

"(IV) a therapeutic recombinant DNA-derived product;

"(viii) a drug required to be refrigerated at any time during manufacturing, packing, processing, or holding; or

"(ix) a photoreactive drug.

''(6) TREATING PROVIDER.—The term 'treating provider' means a licensed health care provider that—

''(A)(i) performs a documented patient evaluation (including a patient history and physical examination) of an individual to establish the diagnosis for which a prescription drug is prescribed;

''(ii) discusses with the individual the treatment options of the individual and the risks and benefits of treatment; and

''(iii) maintains contemporaneous medical records concerning the individual; or

''(B) provides care to an individual as part of an on-call or cross-coverage arrangement with a health care provider described in subparagraph (A).

''(7) WHOLESALER.—

''(A) IN GENERAL.—The term 'wholesaler' means a person licensed as a wholesaler or distributor of prescription drugs in the United States as described in section 503(e)(2).

''(B) EXCLUSION.—The term 'wholesaler' does not include—

''(i) a person authorized to import drugs under section 801(d)(1); or

''(ii) an individual importing a prescription drug under section 812.''.

SEC. 3. COMMERCIAL IMPORTATION.

Subchapter B of chapter VIII of the Federal Food, Drug, and Cosmetic Act, as added by section 2 of this Act, is amended by adding at the end the following section:

''SEC. 812. COMMERCIAL IMPORTATION.

''(a) IN GENERAL.—

''(1) NO PRESUMPTION AGAINST IMPORTATION.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler may import a prescription drug from Canada or a permitted country into the United States for dispensing in the United States unless the importation of the prescription drug is not in accordance with this subchapter.

''(2) LIMITATION TO CERTAIN PORTS.—The Secretary may limit the ports of entry in the United States through which a prescription drug may be imported under this section to a reasonable number of ports designated by the Secretary.

''(b) REQUIREMENTS.—Each prescription drug imported under this subchapter shall—

''(1) be approved under section 505;

''(2) comply with sections 501 and 502;

''(3) be in a container that bears a label stating, in prominent and conspicuous type—

''(A) the lot number of the prescription drug;

''(B) the name, address and phone number of the drug importation facility;

''(C) comply with regulations promulgated by the Secretary to require labeling regarding the fact that the drug is imported; and

''(D) a unique identifier code provided by the Secretary that modifies the national drug code of the prescription drug to indicate that the drug has been imported; and

''(4) comply with any other applicable requirement of this Act.

''(c) APPROVED LABELING.—

''(1) IN GENERAL.—A drug importation facility that offers for importation a prescription drug under this subchapter shall submit to the Secretary an application for approval that demonstrates that the labeling of the prescription drug to be imported into the United States complies with the requirements of sections 502 and 503.

''(2) PROCEDURE.—Not later than 60 days after receipt of a completed application under paragraph (1), the Secretary shall—

''(A) approve or deny the application consistent with the requirements of sections 502 and 503; and

''(B) notify the applicant of the decision of the Secretary and, if the application is denied, the reason for the denial.

''(3) LISTS.—

''(A) APPLICATIONS.—The Secretary shall maintain an updated list of applications pending, applications approved, and applications denied under this subsection.

''(B) PORTS.—The Secretary shall maintain an updated list of ports through which a prescription drug may be imported under this section and make the list available to the public on an Internet website.

''(d) PROHIBITION OF IMPORTATION OF A PRESCRIPTION DRUG THAT ENTERS OTHER COUNTRIES.—

''(1) IN GENERAL.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler shall not import a prescription drug if, during any period in which the prescription drug was not in the control

of the manufacturer, the prescription drug entered a country other than—

"(A) Canada; or

"(B) subject to paragraph (2), a permitted country.

"(2) LIMITATION.—The Secretary may exclude one or more of the countries under subparagraph (B) of paragraph (1) from the application of that subparagraph if the Secretary determines that allowing a prescription drug to be imported into the United States after having entered that country outside control of a manufacturer would present a risk to the public health.

"(e) PROHIBITION OF COMMINGLING.—

"(1) IN GENERAL.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler shall not commingle a prescription drug imported into the United States under this subchapter with a prescription drug that is not imported from Canada or a permitted country.

"(2) LABEL.—A pharmacy or Internet pharmacy that dispenses a prescription drug imported from Canada or a permitted country shall affix on each dispensed container of the prescription drug

the label required under subsection (b)(3) unless such a label is already affixed to the container.

''(f) DRUG RECALLS.—On receipt of notification from the manufacturer of a prescription drug imported from Canada or a permitted country under this section that the prescription drug has been recalled or withdrawn from the market in Canada or a permitted country, a drug importation facility shall promptly provide the Secretary and any person to whom the prescription drug was distributed a notice that the drug has been recalled or withdrawn from the market and that includes—

''(1) information (including the lot number) that identifies the prescription drug; and

''(2) a statement of the reason for the recall or withdrawal.

''(g) CHARITABLE CONTRIBUTIONS.—Notwithstanding any other provision of this section, section 801(d)(1) continues to apply to a prescription drug that is donated or otherwise supplied at no charge or a nominal charge by the manufacturer of the prescription drug to a charitable or humanitarian organization (including the United Nations and affiliates) or to a government of a foreign country.

''(h) JURISDICTION.—The district courts of the United States shall have jurisdiction in an action brought

by the United States against a person importing or offering for importation a prescription drug in violation of the requirements of this section.

''(i) EFFECT OF SECTION.—Nothing in this section limits the authority of the Secretary relating to the importation of prescription drugs (including the interdiction of prescription drugs that are unapproved, adulterated, or misbranded), other than with respect to section 801(d)(1) as provided in subsection (g).''.

SEC. 4. PERSONAL IMPORTATION; INTERNET PHARMACIES.

Subchapter B of chapter VIII of the Federal Food, Drug, and Cosmetic Act, as amended by section 3 of this Act, is amended by adding at the end the following section:

''SEC. 813. PERSONAL IMPORTATION; INTERNET PHARMACIES.

''An individual may, for personal use or for the use of a family member of the individual (rather than for resale), import a prescription drug into the United States from any Internet pharmacy that is registered under section 816 and licensed under section 503B, except to the extent that the Secretary determines that importation of the prescription drug is not in accordance with this subchapter.''.

SEC. 5. PERSONAL IMPORTATION; ENTERING UNITED STATES IN POSSESSION OF PRESCRIPTION DRUGS; COMPASSIONATE USE.

Subchapter B of chapter VIII of the Federal Food, Drug, and Cosmetic Act, as amended by section 4 of this Act, is amended by adding at the end the following section:

"SEC. 814. PERSONAL IMPORTATION; ENTERING UNITED STATES IN POSSESSION OF PRESCRIPTION DRUGS; COMPASSIONATE USE.

''(a) IN GENERAL.—An individual may, for personal use or for the use of a family member of the individual (rather than for resale), import a prescription drug from Canada or a permitted country into the United States, subject to subsections (b) and (c).

''(b) IMPORTATION.—An individual may import a prescription drug if—

''(1) the prescription drug is purchased from a licensed pharmacy in Canada or a licensed pharmacy in a permitted country and dispensed in compliance with the applicable laws of Canada or the permitted country regarding the practice of pharmacy;

''(2) the prescription drug is imported from Canada or a permitted country into the United States;

''(3) the prescription drug is imported by the individual on the person of the individual;

''(4) the quantity of the prescription drug imported does not exceed a 90-day supply during any 90-day period; and

''(5) the prescription drug is accompanied by—

''(A) a copy of a prescription valid in a State and cosigned by a prescribing physician in Canada or the permitted country; or

''(B) if the prescription drug is available in Canada or the permitted country without a prescription, a copy of the valid prescription signed by a pharmacist licensed in Canada or the permitted country.

''(c) COMPASSIONATE USE.—The Secretary may permit an individual to import an up to a 90-day supply of a drug that is not approved by the Secretary under section 505 if the importation is for continuation of personal use by the individual for treatment, begun in a foreign country, of a serious medical condition.''.

SEC. 6. PARTICULAR PRODUCTS; SUSPENSION OF AUTHORITY FOR IMPORTATION.

Subchapter B of chapter VIII of the Federal Food, Drug, and Cosmetic Act, as amended by section 5 of this Act, is amended by adding at the end the following section:

"SEC. 815. PARTICULAR PRODUCTS; SUSPENSION OF AUTHORITY FOR IMPORTATION.

"(a) PRESCRIPTION DRUG.—If the Secretary determines that the importation of a particular prescription drug or particular dosage form of a prescription drug into the United States presents a risk to the public health, the Secretary may immediately order the suspension of the importation of the particular prescription drug or particular dosage form of the prescription drug.

"(b) SUSPENSION.—If the Secretary determines that a drug importation facility, pharmacy, Internet pharmacy, or wholesaler is engaged in a pattern of importing or offering for importation a prescription drug into the United States in violation of any of the requirements of this Act, the Secretary may immediately order the suspension of that person from engaging in the importation or offering for importation of prescription drugs into the United States.

"(c) CANADA OR PERMITTED COUNTRY.—If the Secretary determines that there is a pattern of prescription drugs being imported or offered for importation into the United States from Canada or a permitted country in violation of any of the requirements of this Act, the Secretary may immediately order the suspension of the importation or offering for importation into the United States of pre-

scription drugs from Canada or that permitted country, as appropriate.

''(d) APPEAL OF SUSPENSION ORDER.—

''(1) IN GENERAL.—

''(A) PRESCRIPTION DRUGS.—With respect to the importation of a prescription drug, the importation of which is suspended under subsection (a), any person that would be entitled to be a claimant for the prescription drug may appeal the suspension order to the Secretary.

''(B) SUSPENDED PERSONS.—With respect to a drug importation facility, pharmacy, Internet pharmacy, or wholesaler subject to a suspension order under subsection (b) or (c), the drug importation facility, pharmacy, Internet pharmacy or wholesaler may appeal the suspension order to the Secretary.

''(2) ACTION BY THE SECRETARY.—Not later than 30 days after an appeal is filed, the Secretary, after providing opportunity for an informal hearing, shall confirm or terminate the order.

''(3) FAILURE TO ACT.—If, during the 30-day period specified in paragraph (2), the Secretary fails to provide an opportunity for a hearing or to con-

firm or terminate the order, the order shall be deemed to be terminated.

''(e) NO JUDICIAL REVIEW.—An order under this section shall not be subject to judicial review.

''(f) EFFECT OF SECTION.—Nothing in this section applies to a prescription drug imported by an individual under section 812 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

SEC. 7. REGISTRATION OF IMPORTATION FACILITIES.

(a) IN GENERAL.—Subchapter B of chapter VIII of the Federal Food, Drug, and Cosmetic Act, as amended by section 6 of this Act, is amended by adding after section 815 the following section:

''SEC. 816. REGISTRATION OF CERTAIN IMPORTERS.

''(a) IN GENERAL.—A drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation or offering for importation of prescription drugs into the United States, or in the dispensing of such drugs, shall register with the Secretary in accordance with this section.

''(b) REGISTRATION.—

''(1) IN GENERAL.—To register, the owner, operator, or agent in charge of a drug importation facility, pharmacy, Internet pharmacy, or wholesaler

shall submit to the Secretary a registration that discloses—

"(A) the name and address of each drug importation facility, pharmacy, Internet pharmacy, or wholesaler at which, and all trade names under which, the registrant conducts business;

"(B) the name of each prescription drug to be imported into the United States by each drug importation facility, pharmacy, Internet pharmacy, or wholesaler; and

"(C) the name and address of an agent for service of process in the United States.

"(2) CHANGE IN INFORMATION.—The registrant shall notify the Secretary in a timely manner of any change in the information provided under paragraph (1).

"(3) PROCEDURE.—Not later than 60 days after receipt of a completed registration under paragraph (1), the Secretary shall—

"(A) assign a registration number to each registered drug importation facility, pharmacy, Internet pharmacy, and wholesaler; and

"(B) notify the registrant of the receipt of the registration.

''(4) LIST.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a list of registrants.

''(B) AVAILABILITY.—The Secretary shall make the list described under subparagraph (A) and information submitted by a registrant under paragraph (1) available to the public on an Internet website and through a toll-free telephone number.

''(c) ELECTRONIC FILING.—

''(1) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall provide for, and require the use of, electronic methods of submitting to the Secretary registrations required under this section and shall provide for electronic methods of receiving the registrations.

''(2) AUTHENTICATION.—In providing for the electronic submission of such registrations under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the registrant and validation of the data as appropriate.

''(d) EFFECT OF SECTION.—

''(1) AUTHORITY.—Nothing in this section authorizes the Secretary to require an application, review, or licensing process for a drug importation facility, pharmacy, or wholesaler.

''(2) IMPORTATION BY INDIVIDUALS.—Nothing in this section applies to a prescription drug imported by an individual under section 814 or to a commercial transaction conducted between an Internet pharmacy and an individual.''.

(b) IMPORTATION; FAILURE TO REGISTER.—Section 801 of the Federal Food, Drug, and Cosmetic Act is amended by adding at the end the following:

''(p) FAILURE TO REGISTER.—

''(1) IN GENERAL.—If a drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation or offering for importation of prescription drugs into the United States has not submitted a registration to the Secretary in accordance with section 816, a prescription drug that is being imported or offered for importation into the United States shall not be delivered to the importer, owner, or consignee of the prescription drug until the drug importation facility, pharmacy, Internet pharmacy, or wholesaler is registered in accordance with section 816.

''(2) EFFECT OF SUBSECTION (B).—Subsection (b) does not authorize the delivery of the prescription drug pursuant to the execution of a bond while the prescription drug is held under this subsection.

''(3) REMOVAL.—A prescription drug held under this subsection shall be removed to a secure facility, as appropriate.

''(4) NO TRANSFER.—During the period in which a prescription drug is held under this subsection, the prescription drug shall not be transferred by any person from the port of entry into the United States for the prescription drug or from the secure facility to which the prescription drug has been removed.''.

SEC. 8. ENFORCEMENT; REGULATIONS; EFFECTIVE DATES.

(a) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331) is amended by adding at the end the following:

''(hh) Dispensing or offering to dispense a prescription drug imported into the United States in violation of the requirements of section 812.

''(ii) The importation or offering for importation of a prescription drug in violation of an order under section 815.

''(jj) The failure of a drug importation facility, pharmacy, Internet pharmacy, or wholesaler engaged in the importation or offering for importation of prescription drugs into the United States, or in the dispensing of such drugs, to register in accordance with section 816. ''.

(b) REGULATIONS; EFFECTIVE DATES.—

(1) COMMERCIAL IMPORTATION.—With respect to carrying out section 812 of the Federal Food, Drug, and Cosmetic Act (as added by section 3 of this Act):

(A) The Secretary of Health and Human Services (referred to in this subsection as the ''Secretary'') shall promulgate interim final regulations regarding importation of prescription drugs from Canada not later than 30 days after the date of the enactment of this Act. Such section 812 takes effect regarding the importation of prescription drugs from Canada upon the expiration of such 30 days, without regard to whether the Secretary has promulgated such regulations.

(B) The Secretary shall promulgate interim final regulations regarding importation of prescription drugs from permitted countries not later than one year after the date of the enact-

ment of this Act. Such section 812 takes effect regarding importation of prescription drugs from permitted countries upon the expiration of such one-year period, without regard to whether the Secretary has promulgated such regulations.

(2) PERSONAL IMPORTATION; ENTERING UNITED STATES IN POSSESSION OF PRESCRIPTION DRUG; COMPASSIONATE USE.—The Secretary may promulgate regulations to carry out section 814 of the Federal Food, Drug, and Cosmetic Act (as added by section 5 of this Act). Such section 813 takes effect upon the date of enactment of this Act, without regard to whether the Secretary has promulgated such regulations.

(3) REGISTRATION OF IMPORTATION FACILITIES.—Not later than one year after the date of the enactment of this Act, the Secretary shall promulgate regulations to carry out section 816 of the Federal Food, Drug, and Cosmetic Act (as added by section 7(a) of this Act). The requirement of registration under such section takes effect—

(A) on the effective date of such final regulations; or

(B) if the final regulations have not been made effective as of the expiration of such one-year period, on the date that is one year after the date of the enactment of this Act, subject to compliance with the final regulations when the final regulations are made effective.

SEC. 9. LICENSING OF INTERNET PHARMACIES.

(a) IN GENERAL.—Chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 et seq.) is amended by inserting after section 503A the following section:

"SEC. 503B. LICENSING OF INTERNET PHARMACIES.

''(a) IN GENERAL.—An Internet pharmacy that is licensed in accordance with this section may dispense or offer to dispense a prescription drug to a person in the United States. An Internet pharmacy may not dispense or offer to dispense a prescription drug to such a person prior to obtaining a license under this section.

''(b) DEFINITIONS.—For purposes of this section:

''(1) ADVERTISING SERVICE PROVIDER.—The term 'advertising service provider' means an advertising company that contracts with a provider of an interactive computer service (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f)) to provide advertising on the Internet.

''(2) PERMITTED COUNTRY.—The term 'permitted country' has the meaning given such term in section 811(c).

''(3) PRESCRIPTION DRUG.—The term 'prescription drug' means a drug described in section 503(b) that is approved by the Secretary under section 505.

''(4) INTERNET PHARMACY.—The term 'Internet pharmacy' means a person that dispenses or offers to dispense a prescription drug through an Internet website in interstate commerce in the United States regardless of whether the physical location of the principal place of business of the Internet pharmacy is in the United States or in another country.

''(c) LICENSING OF INTERNET PHARMACIES.—

''(1) IN GENERAL.—The Secretary may issue a license under this section to an Internet pharmacy only if such pharmacy—

''(A) has its principal place of business in the United States, Canada, or a permitted country; and

''(B) meets the requirements of paragraph (2).

''(2) CONDITIONS FOR LICENSING.—

''(A) APPLICATION REQUIREMENTS.—An Internet pharmacy shall submit to the Secretary an application for a license under this section that includes—

''(i)(I) in the case of an Internet pharmacy located in the United States, verification that, in each State in which the Internet pharmacy engages in dispensing or offering to dispense prescription drugs, the Internet pharmacy, and all employees and agents of the Internet pharmacy, is in compliance with applicable Federal and State laws regarding—

''(aa) the practice of pharmacy, including licensing laws and inspection requirements; and

''(bb) the manufacturing and distribution of controlled substances, including with respect to mailing or shipping controlled substances to consumers; or

''(II) in the case of an Internet pharmacy located in Canada or a permitted country, verification that—

''(aa) all employees and agents of the Internet pharmacy are in compliance with applicable laws of Canada or the permitted country regarding the practice of pharmacy, including licensing laws and inspection requirements; and

''(bb) the Internet pharmacy is in compliance with applicable Federal and State laws regarding the practice of pharmacy, including licensing laws and inspection requirements;

''(ii) verification that the person that owns the Internet pharmacy has not had a license for an Internet pharmacy terminated by the Secretary, and that no other Internet pharmacy owned by the person has had a license under this subsection that has been terminated by the Secretary;

''(iii) verification from the person that owns the Internet pharmacy that the person will permit inspection of the facilities and business practices of the Internet pharmacy by the Secretary to the extent necessary to determine whether the Inter-

net pharmacy is in compliance with this subsection; and

''(iv) in the case of an agreement between a patient and an Internet pharmacy that releases the Internet pharmacy, and any employee or agent of the Internet pharmacy, from liability for damages arising out of the negligence of the Internet pharmacy, an assurance that such a limitation of liability shall be null and void.

''(B) IDENTIFICATION REQUIREMENTS.—An Internet pharmacy shall provide to any person that accesses the Internet pharmacy website, on each page of the website of the Internet pharmacy or by a link to a separate page, the following information:

''(i) The street address, city, ZIP Code or comparable mail code, State (or comparable entity), country, and telephone number of—

''(I) each place of business of the Internet pharmacy; and

''(II) the name of the supervising pharmacist of the Internet pharmacy and each individual who serves as a

pharmacist for purposes of the Internet pharmacy website.

''(ii) The names of all States or countries, as appropriate, in which the Internet pharmacy and the pharmacists employed by the Internet pharmacy are licensed or otherwise authorized to dispense prescription drugs.

''(iii) If the Internet pharmacy makes referrals to, or solicits on behalf of, a health care practitioner or group of practitioners in the United States for prescription services—

''(I) the name, street address, city, ZIP Code or comparable mail code, State, and telephone number of the practitioner or group; and

''(II) the name of each State in which each practitioner is licensed or otherwise authorized to prescribe drugs.

''(iv) A statement that the Internet pharmacy will dispense prescription drugs only after receipt of a valid prescription.

"(C) PROFESSIONAL SERVICES REQUIREMENTS.—An Internet pharmacy shall carry out the following:

"(i) Maintain patient medication profiles and other related data in a readily accessible format organized to facilitate consultation with treating providers, caregivers, and patients.

"(ii) Conduct prospective drug use reviews before dispensing medications or medical devices.

"(iii) Ensure patient confidentiality and the protection of patient identity and patient-specific information, in accordance with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(iv) Offer interactive and meaningful consultation by a licensed pharmacist to the caregiver or patient prior to and subsequent to the time at which the Internet pharmacy dispenses the drug.

''(v)(I) Establish a mechanism for patients to report errors and suspected adverse drug reactions.

''(II) Document in the reporting mechanism the response of the Internet pharmacy to those reports.

''(vi) Develop a system to inform caregivers and patients about drug recalls.

''(vii) Educate caregivers and patients about the appropriate means of disposing of expired, damaged, or unusable medications.

''(viii) Assure that the sale of a prescription drug is in accordance with a prescription from the treating provider of the individual.

''(ix)(I) Verify the validity of the prescription of an individual by using 1 of the following methods:

''(aa) Receiving from the individual or treating provider of the individual the prescription of the individual by mail (including a private carrier), or receiving from the treating provider of the individual the prescrip-

tion of the individual by electronic mail.

''(bb) If the prescription is for a controlled substance (as defined in section 102 of the Controlled Substances Act (21 U.S.C. 802)), confirming with the treating provider the information in subclause (II).

''(II) When seeking verification of a prescription of an individual under subclause (I)(bb), an Internet pharmacy shall provide to the treating provider the following information:

''(aa) The full name and address of the individual.

''(bb) Identification of the prescription drug.

''(cc) The quantity of the prescription drug to be dispensed.

''(dd) The date on which the individual presented the prescription to the Internet pharmacy.

''(ee) The date and time of the verification request.

''(ff) The name of a contact person at the Internet pharmacy, including a voice telephone number, electronic mail address, and facsimile telephone number.

''(III) A prescription is verified under subclause (I)(bb) only if 1 of the following occurs:

''(aa) The treating provider confirms, by direct communication with the Internet pharmacy, that the prescription is accurate.

''(bb) The treating provider informs the Internet pharmacy that the prescription is inaccurate and provides the accurate prescription.

''(IV) An Internet pharmacy shall not fill a prescription if—

''(aa) a treating provider informs the Internet pharmacy within 72 hours after receipt of a communication under subclause (I)(bb) that the prescription is inaccurate or expired; or

''(bb) the treating provider does not respond within that time.

''(x) Maintain, for such period of time as the Secretary shall prescribe by regulation, a record of all direct communications with a treating provider regarding the dispensing of a prescription drug, including verification of the prescription.

''(3) LICENSURE PROCEDURE.—

''(A) ACTION BY SECRETARY.—On receipt of a completed licensing application under paragraph (2), the Secretary shall—

''(i) assign an identification number to each Internet pharmacy;

''(ii) notify the applicant of the receipt of the licensure application; and

''(iii) not later than 60 days after receipt of the licensure application, issue a license if the Internet pharmacy is in compliance with conditions under paragraph (3).

''(B) ELECTRONIC FILING.—

''(i) IN GENERAL.—For the purpose of reducing paperwork and reporting burdens, the Secretary shall require the use of

electronic methods of submitting to the Secretary a licensure application required under this section and provide for electronic methods of receiving the applications.

''(ii) AUTHENTICATION.—In providing for the electronic submission of such licensure applications under this section, the Secretary shall ensure that adequate authentication protocols are used to allow identification of the Internet pharmacy and validation of the data as appropriate.

''(4) LIST.—

''(A) IN GENERAL.—The Secretary shall compile, maintain, and periodically update a list of licensees.

''(B) AVAILABILITY.—The Secretary shall make the list described under subparagraph (A) and information submitted by the licensee under paragraph (2)(B) available to the public on an Internet website and through a toll-free telephone number.

''(5) TERMINATION OF LICENSE.—The Secretary, upon the initiative of the Secretary, may terminate a license issued under subsection (c), after

notice to the Internet pharmacy and an opportunity for a hearing, and if the Secretary determines that an Internet pharmacy—

"(A) has demonstrated a pattern of noncompliance with this section;

"(B) has made an untrue statement of material fact in its license application; or

"(C) is in violation of any applicable Federal or State law relating to the dispensing of a prescription drug.

"(6) RENEWAL EVALUATION.—

"(A) IN GENERAL.—Before renewing a license of an Internet pharmacy under this subsection pursuant to the submission of a renewal application, the Secretary shall conduct an evaluation to determine whether the Internet pharmacy is in compliance with this section.

"(B) EVALUATION.—At the discretion of the Secretary and as applicable, an evaluation under subparagraph (A) may include testing of the Internet pharmacy website or other systems through which the Internet pharmacy communicates with consumers, and a physical inspection of the records and premises of the pharmacy.

''(7) CONTRACT FOR OPERATION OF PROGRAM.—

''(A) IN GENERAL.—The Secretary may award a contract under this subsection for the operation of the licensing program.

''(B) TERM.—The duration of a contract under subparagraph (A) shall not exceed 5 years and may be renewable.

''(C) PERFORMANCE REVIEW.—The Secretary shall annually review performance under a contract under subparagraph (A).

''(d) PROVIDERS OF INTERACTIVE COMPUTER SERVICES OR ADVERTISING SERVICES.—A provider of interactive computer services (as defined in section 230(f) of the Communications Act of 1934 (47 U.S.C. 230(f))) or an advertising service provider shall be liable under this section for dispensing or selling prescription drugs in violation of this section on account of another person's selling or dispensing of a prescription drug if the provider of the service—

''(1) accepts advertising for a prescription drug from an Internet pharmacy that is not licensed in accordance with this section; or

''(2) accepts advertising stating that an individual does not need a physician's prescription to obtain a prescription drug.

''(e) REPORTS REGARDING INTERNET-RELATED VIOLATIONS OF FEDERAL AND STATE LAWS ON DISPENSING OF DRUGS.—The Secretary shall, pursuant to the submission of an application meeting criteria prescribed by the Secretary, make an award of a grant or contract to an entity with experience in developing and maintaining systems for the purpose of—

''(1) identifying Internet pharmacy websites that are not licensed in accordance with this section or that appear to be operating in violation of Federal or State laws concerning the dispensing of drugs;

''(2) reporting such Internet pharmacy websites to State medical licensing boards and State pharmacy licensing boards, and to the Attorney General and the Secretary, for further investigation; and

''(3) submitting, for each fiscal year for which the award under this subsection is made, a report to the Secretary describing investigations undertaken with respect to violations described in paragraph (1).''.

(b) PROHIBITED ACTS.—Section 301 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 331), as amended by section 8(a) of this Act, is amended by adding at the end the following:

''(kk) The sale of a prescription drug, or the ownership or operation of an Internet pharmacy, in violation of section 503B.

''(ll) The representation by advertisement, sales presentation, direct communication (including telephone, facsimile, or electronic mail), or otherwise by an Internet pharmacy, that a prescription drug may be obtained from the Internet pharmacy without a prescription, in violation of section 503B.

''(mm) The acceptance of an advertisement from an Internet pharmacy by the provider of an interactive computer service, unless the provider has on file a copy of the license issued to the Internet pharmacy under section 503B.''.

(c) INJUNCTIVE PROCEEDINGS; LINKS TO ILLEGAL INTERNET PHARMACIES.—Section 302 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 332) is amended by adding at the end the following:

''(c)(1) In the case of a violation of section 503B relating to an illegal Internet pharmacy, the district courts of the United States and the United States courts of the

territories shall have jurisdiction to order a provider of an interactive computer service to remove, or disable access to, an Internet website violating that section that resides on a computer server that the provider controls or operates.

''(2) Relief under paragraph (1)—

''(A) shall be available only after provision to the provider of notice and an opportunity to appear;

''(B) shall not impose any obligation on the provider to monitor its service or to affirmatively seek facts indicating activity violating section 503B; and

''(C) shall specify the provider to which the relief applies.''.

(d) IMPORTATION; RETURN TO SENDER.—Section 801 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 381), as amended by section 7(b) of this Act, is amended by adding at the end the following:

''(q) UNLICENSED INTERNET PHARMACY.—If an Internet pharmacy is not licensed by the Secretary in accordance with section 503B, any shipment of a prescription drug from such an Internet pharmacy to an individual shall be refused admission into the United States and the Secretary shall return the prescription drug, other than a prescription drug that is required to be destroyed, to

the Internet pharmacy at the expense of the Internet pharmacy.

''(r) LICENSED INTERNET PHARMACY.—If a shipment of a prescription drug from an Internet pharmacy licensed by the Secretary in accordance with section 503B to an individual is refused admission into the United States, the Secretary shall—

''(1) return the prescription drug, other than a prescription drug that is required to be destroyed, to the Internet pharmacy at the expense of the Internet pharmacy; and

''(2) provide the individual and the Internet pharmacy with a written notice that informs the individual and the Internet pharmacy of the refusal and of the reason for the refusal.''.

(e) REGULATIONS.—With respect to section 503B of the Federal Food, Drug, and Cosmetic Act (as added by subsection (a) of this section):

(1) Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate interim final regulations that are consistent with the Verified Internet Pharmacy Sites certification program developed by the National Association of Boards of Phar-

macy to carry out the amendments made by this section.

(2) The requirement of licensure under such section 503B takes effect on the date determined by the Secretary of Health and Human Services, but in no event later than 90 days after the effective date of the interim final regulations under paragraph (1).

(3) Section 801(q) of such Act (as added by subsection (d) of this section) takes effect on the effective date that applies under paragraph (2) of this subsection.

(4) For purposes of section 813 of such Act (as added by section 4 of this Act), an Internet pharmacy located in Canada is deemed to be licensed under such section 503B pending the effective date that applies under paragraph (2) of this subsection.

SEC. 10. CHAIN OF CUSTODY OF PRESCRIPTION DRUGS; NETWORK FOR NOTIFICATIONS REGARDING COUNTERFEIT DRUGS.

(a) ELECTRONIC TRACK AND TRACE TECHNOLOGY; NETWORK FOR NOTIFICATIONS REGARDING COUNTERFEIT DRUGS.—

(1) ELECTRONIC TRACK AND TRACE TECHNOLOGY.—Not later than December 31, 2007, the Secretary of Health and Human Services shall re-

quire the adoption and use of electronic track and trace technology for a prescription drug at the case and pallet level that will identify each sale, purchase, or trade of that case or pallet (including the date of transmission and the names and addresses of all parties to the transaction).

(2) NETWORK FOR NOTIFICATIONS REGARDING COUNTERFEIT DRUGS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by adding at the end the following:

''(4) The Secretary shall—

''(A) establish a network for the purpose of providing prompt notification to health professionals and the public of counterfeit drugs subject to subsection (b);

''(B)(i) develop and publish an Internet accessible-reference document to facilitate the positive identification by health professionals and regulatory agency personnel of prescription drugs marketed in the United States and Canada; and

''(ii) update the materials described under clause (i) quarterly and when a new permitted country is designated by the Secretary;

''(C) develop and publish educational materials to health professionals and consumers identify and report cases of counterfeit drugs subject to subsection (b);

''(D) develop and publish secure business practice guidelines for the sale and distribution of such drugs in cooperation with members of a drug supply chain; and

''(E) in cooperation with the National Association of Boards of Pharmacy, develop and publish revised model rules for licensure of drug wholesalers for adoption by the States.''.

(3) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this subsection and the amendments made by this subsection, there are authorized to be appropriated such sums as may be necessary for each fiscal year, in addition to other authorizations of appropriations that are available for such purpose.

(b) REQUIRED RECORDS.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by striking ''(e)(1)(A)'' and all that follows through the end of paragraph (1) and inserting the following:

''(e)(1) A distributor of record that is engaged in the wholesale distribution of a drug subject to subsection (b) shall—

''(A) before each wholesale distribution of the drug—

''(i) with respect to each wholesale distribution of a drug subject to subsection (b), provide the person that receives the drug a statement that identifies the immediately previous distributor of record from which the drug was purchased; and

''(ii) with respect to a drug subject to subsection (b) that is imported to the United States, provide the person that receives the drug a statement (in such form and containing such information as the Secretary may require) identifying each prior sale, purchase, or trade of the drug (including the date of transmission and the names and addresses of all parties to the transaction); and

''(B) create, maintain for 2 years, and make available to the Secretary for inspection at reasonable time, records that—

''(i) with respect to each wholesale distribution of a drug subject to subsection (b), identifies—

''(I) the immediately previous distributor of record from which the drug was purchased; and

''(II) the immediately subsequent distributor of record to which the drug was sold or otherwise transferred; and

''(ii) with respect to a drug subject to subsection (b) that is imported to the United States, identifies—

''(I) each previous distributor of record from which the drug was purchased or otherwise transferred; and

''(II) each subsequent distributor of record to which the drug was sold or otherwise transferred, to the extent feasible.''.

(c) DISTRIBUTORS OF RECORD.—Section 503(e) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353(e)) is amended by striking paragraph (3) and inserting the following:

''(3) For the purposes of this subsection and subsection (d)—

''(A) the term 'distributor of record'—

"(i) means a person that takes title to or possession of a drug subject to subsection (b) from manufacture to retail sale;

"(ii) includes a person that manufacturers, processes, packs, distributes, receives, holds, imports, or offers for importation a drug subject to subsection (b); and

"(iii) does not include a transporter;

"(B) the term 'transporter' means the United States Postal Service, or equivalent governmental service of a foreign country, or a private carrier engaged in the business of transporting packages for hire; and

"(C) the term 'wholesale distribution' means the distribution of a drug subject to subsection (b) to other than the consumer or patient but not including an intracompany sale or distribution of a drug described in subsection (c)(3)(B).".

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